

RFA-AI-05-002 Units for HIV/AIDS Clinical Trials Networks

How to Structure the Budget





GRANT WRITING WORKSHOP

- Application Preparation using the Public Health Service (PHS) 398 Form, including information on changes in the newest form, revised 09/2004
- Review of Budget Categories, and
- Discuss selected grants policy and administrative issues

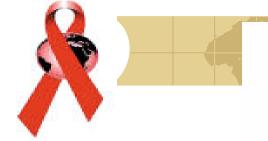




GRANT WRITING WORKSHOP

Application Preparation using the Public Health Service (PHS) 398 Form Revised 09/2004.





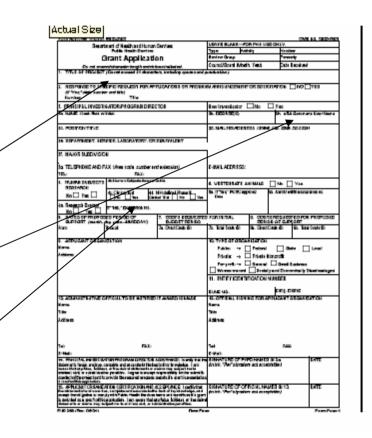
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New Application changes 398 Face Page 09/2004

- NIH now **requires** the use of Arial, Helvetica, Palatino, Linotype or Georgia with font size of 11
- Acceptable Paper Size
- Title—Form field length has been increased to 81 characters
 - eRA Commons User Name field has been added. This data item is currently optional
 - Human Subjects Research box has been modified to include a new data element for Clinical Trials.





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Form Approved Throug	h 09/30/2007							OMB No. 09	325-0001
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3c. POSITION TITLE				3d. MAILING ADDRESS (Street, city, state, zip code)					
3e. DEPARTMENT, SE	RVICE, LABORATORY	, OR EQUIVALENT							
3f. MAJOR SUBDIVISI	ON								
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Name Joe Accountant					Name	Debra D	ean		
Title	Chief, Fin	ancial Office, F	Researc	h Administration	Title	Assistar	nt Dean, Resea	arch A	dministration
Addres	s 123 Intern	ational Drive			Address 123 International Drive				
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14. PRI	NCIPAL INVESTIGA	ATOR/PROGRAM DI	RECTOR	ASSURANCE: I certify that the					DATE
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criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific									
conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.									
 APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and 							FICIAL NAMED I		DATE
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PHS 39	8 (Rev. 09/04)			Face Page					Form Page 1

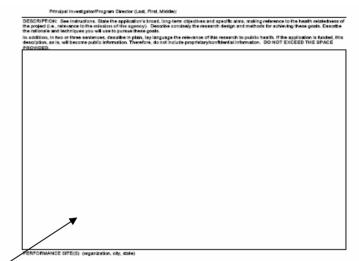




New Application 398 changes

Form Page 2 & Form Page 2 Continued

- ❖ 5 distinct sections—Description, Performance Sites, Key Personnel, Other Significant Contributors, and Stem Cells.
- Description/Abstract: Instructions have been added requiring the PI to succinctly (2-3 sentences) describe the relevance of the proposed research to public health. Plain language is suggested.



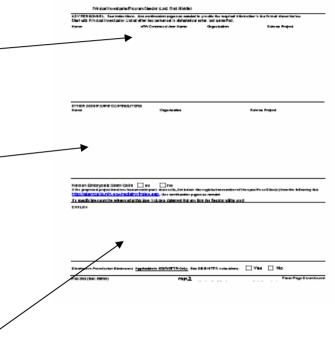
FHS 398 (Rev. 0904) Page 2 Form Page





New Application 398 changes

- Form Page 2 & Form Page 2 Continued
- Key Personnel Section : A field has been added for the eRA Commons User Name.
 - Other Significant Contributors: This is a new field that allows identification of individuals who will contribute to the scientific development or execution of the project but are *not* committing specified measurable effort.
 - Biographical sketches will be required for these individuals;
 - Other Support information will not be required.
 - Human Embryonic Stem Cells: requested as a separate form field.







New 398 Application

PHS Form Page 3

	The name of the principal investigator/program director must	be provided at the top of each printed page and each continuation	page.
	RESE	ARCH GRANT	
	TABLE	OF CONTENTS	
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	jets Pertaining to Consortium/Contractual Arra		
Blog	raphical Sketch – Principal investigator/Program i	Director (Not to exceed four pages)	
Othe	r Biographical Sketches (Not to exceed four pag	ges for each – See Instructions)	
Reso	uroec		
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introde	ction to Revised Application (Not to exceed 3 pages)		
	ction to Supplemental Application. (Not to exceed one page)		
Α.	Specific Aims	·	
	Background and Significance		
O.	Preliminary Studies/Progress Report/	(Rems A-D: not to exceed 25 pages*)	
_	Phase I Progress Report (SBIR/STTR Phase II ONLY)	* SSIR/STTR Phase I: Rents A-D limited to 15 pages.	
	Research Design and Methods		
	Protection of Human Sublects (Required If Item 4 on the Fa		
		e Face Page is marked "Yes" and is Clinical Research)	
		ing dinical research studies)	
		is rearked "Yes")	
	Data and Safety Monitoring Plan (Required if Item 4 on the		
_	Vertebrate Adinals		
	Literature Cled		
	Consortium/Contractual Arrangements		
	Recourse Sharing		
	Letters of Support (e.g., Consultants)		
Co	mmercialization Plan (SBIR/STTR Phase II and Past-Track ON	LY)	
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Appe	mdlx: (Five collated sets. No page numbering necessary for	Appendix.)	Check If
	dices NOT PERMITTED for Phase I SBIR/STTR unless specifi	colly policited	Appendix is included
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		E ID AUDANO 100	
Numb	er of publications and manuscripts accepted for publication. (no her items. dist):		

- Table of Contents PHS398 Form Page 3
- Please Note: pages must be paginated sequentially





Changes in New 398 Application

- Biographical Sketch Format Page: A field has been added for the eRA Commons User Name.
- Personal Data Page: Applicants are now requested to provide only the last four digits of the Social Security Number. Still voluntary.
- Checklist Form Page:
 - Foreign Application: Two distinct options are now provided 1) Grants at Foreign Institutions or 2)
 Domestic Grants with Significant Foreign
 Involvement. This data area also includes a text entry section to list countries involved.





New 398 Application

PHS 398 Budget Form Page 4 for initial budget period and Form Page 5 for entire project period

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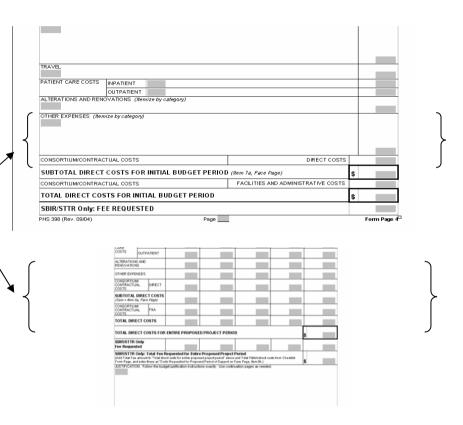




New 398 Application changes

Budget pages 4 and 5

- Budget pages have been modified:
 - Separate the Direct and F &A for Consortium
 - New Subtotal for Direct Costs







GRANT WRITING WORKSHOP

Review of Budget Cost Categories

- Highlight costs specific to foreign applicants, and
- Discussion of selected grants policy and administrative issues





Costs for All Foreign Grantees

- Allowable
- Most of the same costs allowable to domestic grantees including protocol and participant costs
- * "F & A", Facilities and Administrative costs up to 8% less equipment.

- Unallowable
- Customs and import duties, (consular fees, custom surtax)
- Alteration and renovation
- Hospital research patient care rates



Allowable Foreign Unit/Site Costs GNI > USD \$5,000 per capita

- May request allowable expenses:
- Protocol clinical research costs (recruitment, screening, etc.);
- Administrative (P.I., data management, coordinators, essential equipment, supplies, travel & communication costs)
- F & A up to 8% less equipment



Allowable Foreign Unit/Site Costs GNI < USD \$5,000 per capita

- May request all costs allowable for USD > \$5,000 per cap.
- PLUS:
- Additional administrative and facilities expenses such as security costs, power maintenance (generators), transportation (vehicle), necessary to meet project goals





PHS 398 Form Page 4

Principal Investigator/Pro	gram Director (Las	t, First, Midd	se: Gran	t, Apple B.,	MD PhD			
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Steve Coordinator	Site Coordinator	12	100.0					
hy Needle	Clinical Nurse	12	100.0					
Larry Labcoat	Lab/Nurse Assistant	12	100.0					
Cathy Communicator	Interviewer	12	100.0					
TBN	Med.Tech	12	100.0					
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PHS 395 (Rev. 09/04)			Page					Form Page 4

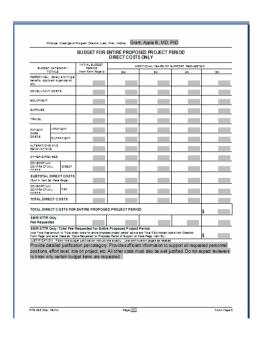
Divides budget into specific cost categories.

Include a breakdown of items within each category.





Budget Categories Form Page 5



- Provides a breakdown of future year costs by category and per year.
- Also includes a section for narrative justification to support your requested budget. Provide justification by categories and items.
- Additional pages will be necessary for thorough justification



Categories for review and discussion

- Personnel
- Consultant
- Travel
- Hospital Research Patient Care
- Other Expenses
- Consortia and subcontracts





Personnel

Principal Investigator/Program Director (Last, First, Middle): Grant, Apple B., MD PhD									
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Steve Coordinator	Site Coordinator	12	100.0						
Ivy Needle	Clinical Nurse	12	100.0						
Larry Labcoat	Lab/Nurse Assistant	12	100.0						
Cathy Communicator	Interviewer	12	100.0						
TBN	Med.Tech	12	100.0						
	SUBTOTALS								
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The people listed here must be employees of the applicant organization (item # 9 on 398 face page)





Personnel Chart Clarification

Principal Investigator/Program Director (Last, First, Middle): Grant, Apple B., MD PhD										
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Carmen Clinician	Resesarch Clinican	12	100.0							
Steve Coordinator	Site/ Coordinator	12	100.0							
Ivy Needle	Clinical Nurse	12	100.0							
Larry Labcoat	Lab/Nurs e Assistant	12	100.0							
Cathy Communicator	Interviewer	12	100.0							
TBN	Med.Tech	12	100.0							
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CONSULTANT COSTS Consultant A 300 hours @	(2) \$50 per hou	r \$15,00	0; Consul	tant B 40 h	ours @ 100 p	per hour				

Months per year employed by applicant organization;

Based on US standard of 40 hours per week-example:50% effort = 20 hours per week. Amount applicant organization pays named employee annually.





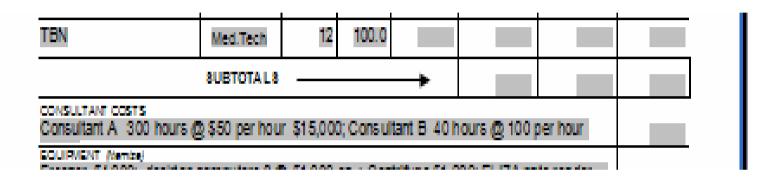
Personnel Fringe Benefits

- In addition to salary some organizations provide Fringe
- Benefits as part of overall compensation to their
- employees.
- Fringe Benefits may include such employee costs as Insurance; Sabbatical Leave; Retirement Savings; and/or Dues and Fees for membership in professional organizations.
- Fringe Benefits are an allowable charge, if they are included in a formally established and consistently applied practice of the applicant organization. Requests for Fringe Benefits must be in proportion to the effort devoted to the project





Consultant Costs



A professional hired to provide advice, guidance or service for a fee. A consultant is NOT an employee of the applicant organization.





Equipment

EQUIPMENT (tembe) Freezer \$4,000; desktop.computers 3 @ \$1,000 ea.; Centrifuge \$1,200; ELIZA pate reader	
SUPPLIES (fembe by category) Chemicals and solvents \$2,500; Laboratory Supplies \$3,500; Disposables \$3,000; Lymphocyte proliferation assays \$7,000; Elispot reagents \$1,500	

- Equipment: Generally defined as an instrument, machine, tool or that can be used for more than one year.
- Request equipment necessary to do the proposed work, itemize cost per item.





Supplies

EQUIPMENT (tembe)	mode (as no particul	
reezer \$4,000; desktop computers 3 @ \$1,000 ea.; Centrituge \$1,	200; ELIZA pate reader	
UPPLIES (tembe by category) Chemicals and solvents \$2,500; Laboratory Supplies \$3,500; Dispos	ables \$3,000;	
ymphocyte proliferation assays \$7,000; Elispot reagents \$1,500		

- Small items and other materials used for project. Examples include chemicals, glassware, etc.
- Itemize requests and include calculation: ELISA kits # of kits X cost per kit = \$ZZ





Travel

TRAVEL Local travel - patier	nt recruitment; visits to sites; participant travel;	
PATIENT CARE (IDSTS	INPATIENT	
	OUTPATENT	
ALTERATIONS AND REN	ONATIONS (tembs by category)	

- Request travel necessary for project. Such as travel to visits sites, participant recruitment.
- Grantees are required to use US Flag carriers or code-share carriers to the extent possible. One exception is travel within a foreign country.





Research Patient Care Costs

Local travel - patient recruitment; visits to sites; participant travel;			
PATIENT CARE COSTS	INPATIENT		
	OUTPATIENT		
ALTERATIONS AND RENOVATIONS (Nambe by category) NVA			- 1
OTHEREXPENSES (famile by oriegory) Equipment conden contracts 100 000; Obligation costs 50 000 Computer and orietor cupalities.			

Definition: Costs of routine and ancillary services provided by hospitals to research participants. Rates are developed for US hospitals and are consistent with US Medicare reimbursement.





Research Patient Care Costs

Local travel - patient recruitment; visits to sites; participant travel;			
PATIENT CARE COSTS	INPATIENT		
	OUTPATIENT		
N/A			
OTHEREXPENSES (for Equipment conden			

Hospital Research Patient Care Rates are for domestic grantees only. All Grantees may request necessary protocol and patient related costs in other budget categories on the PHS 398 form pages.





Recap Research Patient Care

- Definition: Cost of routine and ancillary services provided by hospitals to research participants.
- Rates are developed through DCA for U.S. Hospitals only. Rates are consistent with Medicare reimbursement and include F&A.
- These DO NOT apply to foreign grantees





Examples of Allowable Research Participant / Patient Costs

- research protocol costs
- recruitment costs
- participant incentives and transportation
- clinical screening tests.





Other Expenses

OTHER EXPENSES (tembs by calegory) Equipment service contracts, \$3,000; Shipping costs \$2,000 Computer and printer supplies \$1,000, Telecomunications \$3,000;			
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS		
8UBTOTAL DIRECT C 08T8 FOR INITIAL BUD GET PERIOD (Wern 7s; Face Page)			
CONSORTIUM CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS		
TOTA L DIRECT COSTS FOR INITIAL BUD GET PERIOD		s	

Other items that are necessary for the project. Examples include communication costs, service contracts, lab costs, participant incentives, etc., etc. Itemize costs.





Budget Consortium

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	 22,860
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	(Item 7a, Face Page)	\$ 222,860
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	1 1,430
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		\$ 234,290
SBIR/STTR Only: FEE REQUESTED		
DUG 200 (Dev. 2007A)		E B 4

			•					
NAME	PHS 398 (R)	ev. 09/0	4)					Pi
F Lee Bailey	Investigator	12	10.0	70,000	7,000	750	7,750	
Tina Turner	Research Spec	12	50.0	24,000	12,000	610	12,610	
	SUBTOTALS			→	19,000	1,360	20,360	ı
CONSULTANT COSTS								•
EQUIPMENT (/Tem/Ze)								
							_	
SUPPLIES (Femize by caregory)								
General Laboratory Supp	lies							
							2,000	
TRAVEL								
PATIENT CARE COSTS INPAT								
OUTPATIENT ALTERATIONS AND REMOVATIONS (IRRIDE by Caregory)								
OTHER EXPENSES (Jemice by caegory) Shipping and courier services								
							500	
CONSORTIUM.CONTRACTUAL COSTS DIRECT COSTS						22,860	_ /	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (##m 7a, Face Page)							V	
CONSORTIUM.CONTRACTUAL COSTS FACILITIES AND ADMINISTRATIVE COSTS						11,430		
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD \$					34,290	V		
SBIR/STTR Only: FEE REQUESTED							•	

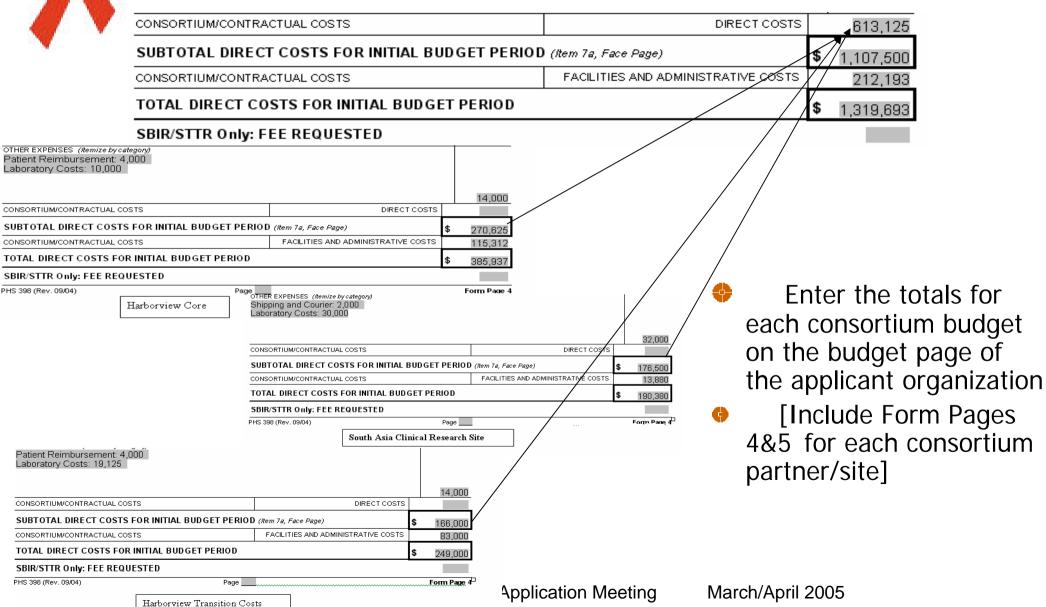
Applications with consortiums will always have at least two Page 4 and 5

- 1. For the application which includes the totals for each consortium budget
- 2. For each consortium



CONSORTIUM

Detail of Form Page 4 con't





Consortium Definition

- **A** Consortium is a collaboration between the Applicant Organization and another Organization that contributes to the research project.
- **A separate budget using PHS form pages 4 & 5 are required for the Consortium Organization**

ALLOWABLE COSTS in consortiums:

Direct Costs are the same types of costs as the host organization Indirect Costs or Facilities and Administrative Cost.

For U.S. Institutions: use their negotiated rate; Non-US Institutions are allowed up to 8% applied to direct costs less equipment.





Consortium Agreements

- A written agreement between the applicant and consortium organizations, must be negotiated in accordance with NIH Grants Policy requirements.
- These agreements must be directly between the applicant organization and each consortium partner organization





Consortium Agreements, con't.

- Note: a consortium partner's budget may not include a subcontract. This is called a "third tier" relationship.
- Third tier relationships are not allowed, however purchased service contracts are.
- Actual consortium vs. purchased service or service contract





Grant Writing Workshop Questions?

